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MAY - 2 2011

Section 5 - 510(k) Summary

Date of Summary Preparation: 11/22/2010

1. Submitter's Identifications

Submitter's Name: ZHONGSHAN TRANSTEK ELECTRONICS CO., LTD.
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2. Correspondent's Identifications

Correspondent's Name: A03 Lab of BTS
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3. Name of the Device

Device Classification Name: Analyzer, Body Composition (Impedance Plethysmograph)
Product Name: TRANSTEK Glass Body Analyzer
Trade Name: Transtek
Models: GBF-830, GBF-835, GBF-950, SA-15
Classification Panel: Cardiovascular
Common/Usual Name: Body Composition Analyzer/Scales
Product Code: MNW
Device Classification: Class II
Contraindications: Do not use the Analyzer if you have a pacemaker or other internal medical device.

4. The Predicate Devices

Fook Tin, Scaleman Body Fat Scales, Model FS-148BW1, K083838

5. Device Description

The TRANSTEK Glass Body Analyzer uses BIA (Bio Impedance Analysis) technology which passes an electrical current through the body to estimate body fat mass, lean mass, total body water and bone

mass. The electrical current is small and may not be felt. Contact with the body is made via glass and stainless steel pads on the platform of the analyzer.

This method simultaneously calculates your personal weight, body fat, total body water, bone mass and muscle mass, giving you a more accurate reading of your overall health and fitness.

This scale stores the personal data of up to 8 or 10 users. As well as being an analyzer, this device can be used as a conventional scale.

6. Intended Use of Device

The Transtek Glass Body Analyzer measure weight and uses bioelectrical impedance analysis (BIA) technology to estimate body fat, total body water percentage, bone mass, and muscle mass in generally healthy adults 18 years of age or older. It is intended for use in the home/domestic setting only.

7. Summary of Substantial Equivalence

Table 1: The difference between TRANSTEK Glass Body Analyzer and the predicate device, Scaleman Body Fat Scales (Model FS-148BW1)

Feature	**Proposed Device: TRANSTEK Glass Body Analyzer Models: GBF-830, GBF-835 GBF-950, SA-15**	**Predicate Device: Scaleman Body Fat Scales Model: FS-148BW1**
510(k) Number	K102191	K083838
Manufacturer	ZHONGSHAN TRANSTEK ELECTRONICS CO., LTD	Fook Tin Technologies Ltd.
Classification	21 CFR 870.2770	21 CFR 870.2770
Product Code	MNW	MNW
Indication for use	The Transtek Glass Body Analyzer measure weight and uses bioelectrical impedance analysis (BIA) technology to estimate body fat, total body water percentage, bone mass, and muscle mass in generally healthy adults 18 years of age or older. It is intended for use in the home/domestic setting only.	The Scaleman Body Fat Scales-Models in "Family Model List 1A" is a series of body composition analyzers that measure body weight and impedance and estimate percentage of body fat and body water using BIA (bioelectrical impedance analysis). They are intended for use by healthy children 10-17 years old and healthy adults with active, moderately active, to

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	mass, muscle mass and body fat simultaneously, thus giving you a more accurate reading of your overall health and fitness. It is not intended for use by pregnant women or children under the age of 18.	healthy children 10-17 years old and healthy adults with active, moderately active, to inactive lifestyles for body composition assessment in the home environment. The Scaleman Body Fat Scales - Models in 'Family Model List 1B" is a series of body composition analyzers that measure body weight and impedance and estimate percentage of body fat and body water, bone mass and muscle mass using BIA (bioelectrical impedance analysis). They are intended for use by healthy children 10-17 years old and healthy adults with active, moderately active, to inactive lifestyles for body composition assessment in the home environment.
Device description	TRANSTEK Glass Body Analyzer utilizes a "foot-to-foot" bioelectrical impedance analysis (BIA) technology to determine internal body composition.	Scaleman Body composition analyzer/scale that utilizes a "foot-to-foot" bioelectrical impedance (BIA) technology to determine internal body composition.
Analysis method	BIA (Bioelectrical Impedance Analysis)	BIA
Operating parameters	50 KHz	50 KHz
Power source	GBF-830, 4*AAA GBF-835, 2*CR2032 GBF-950, 4*AAA SA-15, 2*AA	Replaceable 9V or CR2032 or AAA batteries, depending on the model.
Operating keys	GBF-830, GBF-835, GBF-950 (4), SA-15 (3)	Range of 3 to 6, depending on the model
Number of electrodes	4	4 or 2

8. Conclusions

The subject devices have all features of the predicate device, Scaleman Body Fat Scales (Model FS-148BW1) except the new features and the power source voltage of the device. These differences do not affect the safety and effectiveness of the subject devices. BIA (Bioelectrical Impedance Analysis) technology is same as what is used in Scaleman Body Fat Scales (Model FS-148BW1). Thus, the subject devices are substantially equivalent to the predicate devices.

--- End of this Section ---

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G60
Silver Spring, MD 20993-0002

ZHONGSHAN TRANSTEK ELECTRONICS CO., LTD.
c/o Mr. Leo Wang
Consulting Manager
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No. 1 Fanghua Street, Hi-tech District
Chengdu Sichuan 610041
CHINA

MAY - 2 2011

Re: K102191
Trade/Device Name: TRANSTEK GLASS BODY ANALYZER
Models: GBF-830, GBF-835, GBF-950, SA-15
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: April 8, 2011
Received: April 19, 2011

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Indications for Use

510(k) Number (if known): K102191

Device Name:

TRANSTEK GLASS BODY ANALYZER
Models:GBF-830, GBF-835,GBF-950,SA-15

Indications for Use:

The Transtek Glass Body Analyzer measure weight and uses bioelectrical impedance analysis (BIA) technology to estimate body fat, total body water percentage, bone mass, and muscle mass in generally healthy adults 18 years of age or older. It is intended for use in the home/domestic setting only.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102191

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